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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,505	10/16/2003	Christine Noel	231893US0	5083
22850 7590 09/30/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER YU, GINA C				
ART UNIT 1617		PAPER NUMBER		
NOTIFICATION DATE 09/30/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary

Application No.

10/685,505

Applicant(s)

NOEL ET AL.

Examiner

GINA C. YU

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 8-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment filed on May 28, 2010. Claims 1, 6, 8-18, 20-24 are pending. Claims 1, 6, 8-18 and 20 are examined on merits, and claims 21-24 have been withdrawn from consideration according to restriction requirement originally made on November 30, 2005 and applicant's election dated on May 8, 2006.

Claim rejection made under 35 U.S.C. § 103 (a) as being unpatentable over Robinson et al. (WO 02/03952) in view of Stolz (FR 2771632 or US 2001/00022597), which was indicated in Office action dated November 30, 2009, is withdrawn in view of applicant's claim amendment.

Claim rejection made under 35 U.S.C. § 103 (a) as being unpatentable over Lorant et al. (EP 1055406 or US 6,465,402) in view of Fotinos (US 6,346,255), which was indicated in the same Office action, has been modified to address the claim amendment. The previous grounds of rejection are maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6, 8-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorant et al. (EP 1055406 or US 6,465,402, the English equivalent) in view of Fotinos (US 6,346,255).

Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The prior art oil-in-water emulsions are stable and do not contain any conventionally used

surfactant. See col. 2, lines 12-28; instant claim 1. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is advantageous to formulate an emulsion without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable feel during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36.

Lorant teaches the use of α , ω dimethylvinylpolydimethylsiloxane. See column 4, line 50. The elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66; instant claims 8-10. The water-soluble polymers that are suitable include carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid (AMPS), in particular the mixture sold under the name Sepigel 305; instant claims 12-15. The polymer is used in an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40; instant claim 16. The oils in the oil phase include non-volatile and volatile oils; the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25; instant claims 17-18. The composition comprises active agent in the amount of 0.01-30%, which may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active principle appropriate for the final purpose of the composition.

See column 10, lines 32-60. The composition is suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

Lorant does not teach the use of the instant lipophilic amino acids.

Fotinos teaches a method of improving skin appearance with a skin permeation enhancer and an active agent. See abstract. Fotinos teaches the use of various lipoamino acids such as acylation products, which are anti-elastase and anti-collagenase agents (anti-wrinkle agents); the use of lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seborégulators; lipoamino acids such as lysine PCA and related compound as hydratives. See column 7, lines 36-65. Examples 37-40 teaches cosmetic pads containing seborégulators, wherein the active ingredient is used at 1 % w/w on a dry basis and at 16.13 % by weight of coating compositions. See examples 38 and 40. The reference also indicates that cosmetic actives are typically present in cosmetic pads in an amount of 1-20 % by weight. See col. 8, lines 38 – 55; instant claim 6. Furthermore, the reference teaches that it is a conventional practice in cosmetic art to formulate cosmetic agents in various forms, either in lotion or patches. See col. 4, lines 60-66. Thus discovering the workable effective amount for the seborégulators in a liquid vehicle would have been well within the skill of the art.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Lorant and Fotinos and utilize lipoamino acids as the active agent in Lorant's composition. One would have been motivated to

do so since Fontinos teaches lipoamino acids have a large number of applications in the cosmetic field including anti-wrinkle agents, antioxidants, hydrating agents, and seoregulators and Lorant teaches the use of any skin active agent including antioxidants and moisturizing agents, depending on the final purpose of the composition. Therefore, the selection of the active agent is prima facie obvious depending on the desired aesthetic benefit provided by the skin care composition. Furthermore, a skilled artisan would have been motivated to use capryloyl glycine in particular if one desired to provide a composition that controls sebum, which causes acne.

With respect to claim 6, finding a workable weight amount of capryloyl glycine in the Lorant emulsion would have been well within the skill of the art. The court in In re Aller has stated, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, the Fontinos teaches the general range of cosmetic active ingredient for cosmetic patch or pad, and teaches that seoregulators are used in 16.13 % by weight of a coating composition or 1 % by dry weight. Also suggested in the reference is the conventional practice in cosmetic art that same cosmetic actives are incorporated into different formulations, such as lotion. Since Fontinos teaches capryloyl glycine is used in cosmetics to control sebum, the parameter for the optimization of the weight amount is clearly taught. Thus discovering the optimum weight amount of the capryloyl glycine as

a sebum regulator in the Lorant silicone emulsion would only take routine experimentations in the art.

Response to Arguments

Applicant's arguments filed May 28, 2009 have been fully considered but they are unpersuasive.

Lorant in view of Fotino

Applicant asserts that the presently claimed composition is stable as the result of using capryloyl glycine and undecylenoylglycine. Applicant also states, "[n]o stabilizing effective amount of surfactant is present in the invention compositions, meaning that irritation resulting from the presence of surfactant is not associated with the invention composition. The applied art neither teaches nor suggests such specific, stabilized emulsions."

Examiner respectfully disagrees with applicant's assessment of the prior arts. Lorant is specifically directed to a surfactant-free oil-in-water emulsion that comprises at least one hydrophilic polymer and at least one crosslinked solid organopolysiloxane elastomer just as used in the present invention. Lorant states that hydrophilic polymers generally form gelled matrix which "serves to set the oily droplets and mechanically maintains the entire emulsion". See col. 1, lines 47-51. The combination of the specific hydrophilic polymer and at least crosslinked silicone elastomer is already known to produce a stable oil-in-water emulsion without any emulsifying surfactant.

Prior art Example 1 contains AMPS, 3 wt % KSG21 (28% active, i.e., 0.84 wt % of active material) and volatile silicone and resulted in a "stable and slightly translucent cream" which is "fine and even under the microscope".

Applicant also argues that oil-in-water emulsions containing at least 1 % elastomeric organopolysiloxane and hydrophilic polymer(s) tend toward destabilization. Applicant asserts that Examples 3-6 as shown in the present specification and Rule 132 declarations submitted July 24, 2007 and November 1, 2006 show unexpected property of the claimed glycine derivatives to stabilize o/w emulsions containing at least 1 % elastomeric organopolysiloxane and hydrophilic polymers without surfactant. However, Lorant Example 4 has already illustrated a surfactant-free emulsion which is stabilized by organopolysiloxane elastomer gel contained in an amount greater than 1wt% of the total composition (i.e., 1.32 % active). See also col. 5, lines 59-67, which teaches the organopolysiloxane elastomer concentration range of 0.01-10%, and more preferably 0.5-5 % by weight with respect to the total weight of the composition.

Examiner notes the different conditions employed in the process of making the prior art and the present invention. The present invention requires heating the aqueous phase and then cooling the emulsion after mixing. See applicant's spec., Example 1. On the other hand, Lorant stabilized the O/W emulsion surfactant free at room temperature. See Examples; col. 10, lines 25 – 31. Since applicant's invention is a composition of matters, at issue is whether applicant has shown any unexpected or surprising result from the combination of the particular claimed components. In this case, Lorant already has achieved stabilizing an O/W emulsion surfactant free by

combining a hydrophilic polymer and at least 1 % of elastomeric organopolysiloxane dispersed in oil. Fontino further teaches motivation to use applicant's glycine derivatives in cosmetic emulsions for the known cosmetic/therapeutic benefits. Therefore, examiner views that the claimed composition comprising the glycine derivatives "in an amount sufficient to stabilize the composition", when the composition already has been known to be stable, is not viewed as a surprising or unexpected product.

With respect to Fontino, applicant argues that the prior art teaching is limited to using the disclosed glycine derivatives in patch or pad. Applicant asserts that the reference fails to provide any teaching or suggestion to add the glycine derivative to an emulsion in a stabilizing effective amount. However, the Fontino specifically mentions that formulating cosmetic agents in various forms, including lotion or patches, would have been an obvious practice. Combining the teachings of Lorant/Fontino to arrive to the composition of the present claims would have been obvious to a person of ordinary skill in the art.

Robinson in view of Stolz

Applicant's remarks with respect to the rejection are rendered moot, as the rejection has been withdrawn in view of the claim amendment.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydown G. Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1617